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A PROFESSIONAL CORPORATION

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April 17, 1998

Via Facsimile and Cert. Mail RRR # P 436 556 654

Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Drive, Room 1-23
Rockville, MD 20857

RE: International Drug Scheduling; Convention on
Psychotropic Substances; Dihydroetorphine; Ephedrine;
Remifentanyl; Isomers of Psychotropic Substances
[Docket No. 98N-0148].

Dear Sir or Madam:

I write on behalf of Omnitrition International, Inc. ("Omnitrition") in response to a notice published by the Food and Drug Administration on March 18, 1998, requesting interested persons to submit data or comments concerning abuse potential, actual abuse, medical usefulness, and trafficking of three drug substances, including ephedrine (the "Notice").

Omnitrition does not manufacture, distribute or sell drugs. However, it does distribute herbal tea which contains an extract from the botanical herbal ephedra. As Omnitrition understands the FDA's request, the World Health Organization ("WHO") is seeking information related to the drug ephedrine and not the ephedra herb. Omnitrition also understands that the FDA has previously taken the position that ephedra herbal products are to be considered dietary supplements under the Dietary Supplement Health and Education Act. However, out of an abundance of caution and in an effort to alleviate any future concerns or misunderstandings, Omnitrition submits the following comments related to its ephedra herbal products.

Extracts removed from the ephedra herb contain various levels of the following alkaloids: ephedrine, pseudoephedrine, norephedrine, norpseudoephedrine, n-methylephedrine, and n-

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methylnpseudoeephedrine. Ephedra herbal teas, including Chinese Ma Huang tea and Mormon tea, have been consumed safely by populations the world over for the past 5,000 years. The herb appears in the 1569 A.D. pharmacopeia, The Chinese Dispensatory (Pentsao Kang Mu). The herb was used in Russia for many centuries. It has also been employed by the Indians and Spaniards of the Southwest United States. Herbal products containing ephedra have a long history of safe use as foods and dietary supplements.

The amount of actual ephedrine alkaloid extracted from the ephedra herb in relation to the raw herb is minute. Accordingly, those who manufacture methamphetamine and methcathinone do not use the ephedra herb, but rely apparently on synthetic ephedrine derived from OTC drugs. Dr. Varro Tyler, one of the nation's leading experts on herbs, has recognized distinction between ephedra herb and synthetic ephedrine:

Because of its chemical structure, ephedrine can serve as a precursor for the illegal synthesis of methamphetamine or "speed," a common drug of abuse. Several states have recently passed laws regulating the sale of the alkaloid or products containing it. This concern overlooks the fact that today most ephedrine is produced by a chemical synthesis involving the reductive condensation of L-1-phenyl-1-acetylcarbinol with methylamine. This yields the desired isomer L-ephedrine that is identical in all respects to that contained in ephedra. In view of the difficulties involved in extracting and purifying the relatively small concentrations of ephedrine from the ephedra herb, and the fact that the plant serves only as a minor source of the alkaloid anyway, restricting the availability of the herb, although well intended, seems an excessive measure [city M. Weiner, 37 *Health Foods Business* 8, 12 (1991)].

Omnitrition is unaware of any instance in which its products, or any other herbal product containing ephedra or its alkaloids, were converted into, or used to manufacture methamphetamine or methcathinone. Indeed, Omnitrition has been

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informed that such a conversion process would extremely difficult and economically unfeasible.¹

The powder used in Omnitrition's ephedra herb tea contains 20 milligrams of ephedra alkaloids (of which approximately half is the ephedrine alkaloid) from 334 mg of ephedra herb extract (the amount of which is varied to standardize the ephedrine content per serving of tea at six percent 6%). Omnitrition's ephedra herbal tea contains approximately 11 grams of total ingredients consisting of several other herbs, vitamins, minerals, flavor extracts, sugars, and other food ingredients. Accordingly, the ephedrine content of the Omnitrition's herbal tea is less than 0.2%. Moreover, a plethora of solvents would be required to extract ephedrine from herbal ephedra products. Accordingly, the extraction of just 10 kilograms of ephedrine would require about 10,000 kilograms of herbal tea and about 100,000 to 200,000 kilograms of solvents - an operation that is neither economically feasible nor capable of being hidden from the authorities. In addition, Omnitrition's ephedra herb tea sells for approximately one dollar per serving, making the already impossible process prohibitively expensive.

In conclusion, Omnitrition supports the responsible regulation of OTC drugs, however, Omnitrition requests that FDA recommend to the WHO that ephedra herbal teas, as well as other ephedra herb products, should not be declared a controlled substance or treated as such. Thank you for your consideration into this matter.

Sincerely,



Scott D. Levine
Counsel for Omnitrition
International, Inc.

SDL:mew

¹Omnitrition requested that the formulator of its ephedra herbal tea comment on the issues raised by the FDA and further contract with an independent qualified and licensed laboratory to confirm their comments. Attached hereto is a letter Omnitrition has received in response to its requests.

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16 April 1998

Subject: Response to accusations by FDA and DEA regarding illicit conversion of ephedra herb in products like *OmniTrim Extra* into methamphetamine, and proposed regulatory action.

Scott D. Levine
Banowsky, Betz & Levine
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2323 Bryan Street
Dallas, Texas 75201

Dear Mr. Levine,

This is in response to your question regarding the allegation by FDA and DEA that ephedra-herb-containing teas like *OmniTrim Extra* have potential for illegal diversion into illicit methamphetamine manufacture, and the agencies' plans to initiate regulatory action.

Ephedra herb does, in fact, contain very small amounts of ephedrine. However, I am aware of *no* reported cases in the scientific or forensic literature of an ephedra herb-containing dietary supplement or food being used for the illicit manufacture of methamphetamine. There have, however, been *numerous* cases where FDA-approved OTC ephedrine pills have been diverted to such manufacture. The reason for this difference is simple: It is extremely difficult and entirely unprofitable to convert ephedra herb into methamphetamine—and relatively easy and quite profitable to convert FDA-approved OTC ephedrine pills into methamphetamine.

For example, a typical FDA-approved OTC ephedrine tablet contains about 50 milligrams of ephedrine, and 150 milligrams of inert tablet filler-binder. This gives an ephedrine content of 25%. Ephedrine can be quickly, easily and economically extracted from such tablets and separated from the inert and frequently insoluble tablet filler-binder, using a small amount of solvent.

Each serving of *OmniTrim Extra* (11 grams, or 11,000 mg!) in contrast, contains 20 mg of ephedra alkaloids. That is a concentration of less than 0.2 % (!!) ephedra alkaloids. The remainder of the product consists of fructose, malic acid, natural fruit flavors, vitamins A, C, and E, as well as Red Tea Extract (as a source of caffeine—approximately 100-150 mg—about the same as in a cup of coffee), and tyrosine, taurine, and ferulic acid.

Because of this low concentration of ephedra alkaloid in *OmniTrim Extra*, at least 200 times as much solvent would be required to extract ephedrine from the herbal tea, than is needed to extract ephedrine from a typical ephedrine tablet. Furthermore, the equipment required to extract ephedrine from herbal tea would have to be at least 200 times larger than that required to extract ephedrine from tablets. Indeed, the extraction of just 10 kilograms of ephedrine would require about 10,000 kilograms of herbal tea and about 100,000 to 200,000 kilograms of solvents--an operation that is neither economically feasible nor capable of being hidden from the authorities. Moreover, many of the other constituents of ephedra herb tea are far more difficult to separate from ephedrine than the simple tablet fillers and binders (such as dicalcium phosphate) found in ephedrine tablets.

In summary, the overwhelming disadvantages and complications of trying to extract ephedrine from ephedra herb include: (1) far greater cost (at least 200 times more for solvents to extract ephedrine from the herb as opposed to the tablet); (2) the economic and practical infeasibility of purchasing and storing such a large quantity of solvents (without arousing suspicion); (3) vastly greater cost (at least 200 times more) for processing ephedrine from the herb; (4) far greater difficulty and cost and far lower efficiency associated with extracting ephedrine from such a dilute, complex mixture; and (5) vastly greater difficulty and cost associated with maintaining a clandestine cover for the large extraction and purification equipment and the extraordinary quantity of solvents (to say nothing of disposing of the 100 to 200 tons of used solvents afterward!).

In addition, *OmniTrim Extra* sells for fifty cents to one dollar per serving. Thus, the cost per milligram of ephedrine is about 50 to 100 times higher than ephedrine tablets. It is clear that no one with the intelligence and skill required to perform this sophisticated analytical feat would be stupid enough to expend the time, money and effort to extract ephedrine from *OmniTrim Extra* herbal tea and refine it into illicit methamphetamine. Consequently, it is not at all surprising that ephedra herb from *OmniTrim Extra* herbal tea has *never* been diverted to methamphetamine manufacture, nor is it at all likely that it would ever be used in such an illicit manner.

We are in the process of obtaining an independent laboratory opinion on this matter and will forward a copy of their response.

If you have any other questions, please let me know,

Yours truly,

Ward Dean, M.D.
Director, Research and Development
Vitamin Research Products, Inc.
Carson City, Nevada

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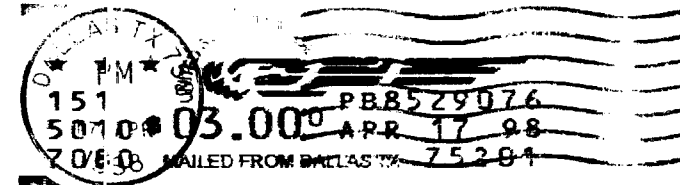
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Handwritten signature/initials

